IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NEVRO CORP., Plaintiff, v. STIMWAVE TECHNOLOGIES, INC., Defendant.	C.A. No. 19-325-CFC

DECLARATION OF WILLIAM S. ROSENBERG
IN SUPPORT OF NEVRO'S MOTION FOR PRELIMINARY INJUNCTION

I, William Sanford Rosenberg, hereby declare as follows:

1. I have been retained to testify as an expert on behalf of Plaintiff Nevro Corp. ("Nevro"), in the above captioned case. I submit this declaration in support of Nevro's Motion for Preliminary Injunction. I have personal knowledge of the matters set forth in this declaration and, if called to testify as a witness, could and would do so competently.

I. BACKGROUND AND QUALIFICATIONS

2. I am a neurosurgeon specializing in pain care. I currently practice with Midwest Neurosurgery Associates in Kansas City, Missouri.

3. I received my M.D. from Harvard Medical School in 1987. Before that, I graduated from the College of Creative Studies, part of the University of California, Santa Barbara, in 1982.

4. I completed my residency in 1993, at the Massachusetts General Hospital Department of Neurosurgery. I was the chief resident at the Massachusetts General Hospital Department of Neurosurgery in 1993.

5. From 1994 through 1998, I practiced with the Mayfield Clinic in Cincinnati, Ohio. During that time, I held privileges at many hospitals, including University Hospital, Good Samaritan Hospital, Christ Hospital, Children's Hospital Medical Center, and the Veteran Administration Medical Center. From 1998 through 2002, I practiced at the Department of Neurosurgery, University of California, San Francisco, during which time I held privileges at UCSF Medical Center, Mt. Zion Hospital, and the Veterans Administration Medical Center in San Francisco, California. From 2002 through the present, I have practiced at Midwest Neurosurgery Associates in Kansas City, Missouri, holding privileges at Research Medical Center and Menorah Medical Center. From 2010 through 2011, I also held privileges at St. Luke's Health System in Kansas City, Missouri.

6. I have also held many faculty positions over the years. In 1994, I was an Assistant in the Department of Neurosurgery at Massachusetts General Hospital. From 1994 through 1998, I was an Assistant Professor in the Department of Neurosurgery at the University of Cincinnati College of Medicine, where I also held the positions of Director, Division of Neurotrauma and Critical Care (1994-97), Research Director, Center for Computational Neurobiology and Adjunct Assistant Professor, Department of Aerospace Engineering and Engineering Mechanics, College of Engineering. From 1998 through 2002, I was both Assistant Professor-in-Residence and Co-Director of the Neurospinal Disorders Program with the Department of Neurological Surgery at the University of California San Francisco School of Medicine. And from 2004 through 2009, I was Medical Director of the Menorah Medical Center CyberKnife Center for Menorah Medical Center, Overland Park, Kansas. I am currently Assistant Professor in the Department of Surgery, University of Missouri – Kansas City School of Medicine. I have taught numerous courses on various subjects related to neurosurgery over the years and have supervised the research and theses of several graduate students over the years.

7. I have been a member of the American Association of Neurological Surgeons since 1993, a member of the Congress of Neurological Surgeons since 2000, a member of the North American Neuromodulation Society and the International Neuromodulation Society since 2009, a member of the American Academy of Pain Medicine since 2011 and a member of the American Society for Stereotactic and Functional Neurosurgery since 2013. I have been on the Executive Council of the American Association of Neurological Surgery/Congress of Neurological Surgery Joint Section on Pain since 2013, serving as Secretary/Treasurer from 2015 to 2017 and currently holding the office of Vice Chair. I am the Founder and President Emeritus of the Cancer Pain Research Consortium.

8. I have spoken and taught extensively on the subject of neurostimulation, serving as Invited Faculty at many symposia and delivering Grand Rounds in a number of venues, including Harvard Medical School.

9. I have personally implanted or revised between 1,500 and 2,000 SCS systems in patients. I have implanted systems manufactured by Boston Scientific, St. Jude (now Abbott), Medtronic, and Nevro. My first experience implanting and treating a patient with an SCS system was in 2009. It has been a regular part of my practice in treating patients with chronic pain since that time; I regularly implant approximately 10-25 SCS systems per month.

10. The first time I personally implanted a Nevro system was in 2015. Prior to that, the majority of my neurostimulation practice consisted of St. Jude Medical implants, a minority of Medtronic implants, and a few systems using Boston Scientific. Since starting to use the Nevro Senza system and its HF10 therapy, and seeing the tremendous clinical advantages to both patient and physician, the vast majority of my neurostimulation practice (80-90%) has changed to using Nevro implants.

11. I am being compensated for my time spent on this case at the rate of $1,000 per hour. I have also been compensated for other matters related to Nevro, including serving as an expert witness in the case of *Nevro Corp. v. Boston Scientific et al.,* Case No. 3-16-cv-06830-VC-MEJ in the Northern District of California, and non-litigation matters as well as consulting consisting of speaking engagements, teaching cadaver courses and evaluating paddle lead design.

12. My full C.V. is attached to this declaration as Exhibit 1.

II. DIFFERENCES BETWEEN NEVRO'S THERAPY AND TRADITIONAL LOW FREQUENCY SCS THERAPY

A. Low Frequency Spinal Cord Stimulation

13. Traditional low frequency spinal cord stimulation ("LF SCS") is accomplished by placing leads in the epidural space, overlying the dorsal (posterior) spinal cord. These provide electrical current that stimulates the dorsal columns of the spinal cord. These are fibers that carry information on touch and joint position sense to the brain. Stimulating them produces paresthesia, a sensation that has been described in a variety of ways, including a tingling sensation, feeling of pins and needles, like the area has fallen asleep, as a warming feeling, or a pinching or poking feeling.

14. Over the decades that LF SCS has been clinically available, it has been thought that successful pain control is critically dependent on delivering the electrical stimulation to the fibers that carry sensation from the area of pain. This is determined by the location of the paresthesia, which must, to the extent possible, overlay the painful area. For this reason, the patient must almost always be awake during placement of the leads during the operating procedure to provide feedback on the location of the paresthesia, allowing the physician to adjust the location of the leads accordingly. This can be a very laborious and sometimes frustrating process. Moreover, there can be circumstances in which it is difficult or even impossible to achieve this goal, either because of normal variation in patient anatomy or for certain specific locations (e.g., low back pain).

15. Fundamentally, successful LF SCS is predicated on replacing the painful sensations with paresthesias. Paresthesias are not a side effect of LF SCS therapy, but the means by which the therapy works. As was observed in a 2007 paper co-authored by a Boston Scientific principal scientist and published about a study sponsored by Boston Scientific:

"Patient-perceived concordant paresthesia overlapping the area of pain is *essential* for success of this therapy."[1] (emphasis added.) A paper written by Dr. Laura Tyler Perryman, Stimwave's CEO, also recognizes that generating paresthesia is fundamental to traditional low frequency SCS therapy: "[a]lthough paresthesia elicited by SCS may not necessarily relate to the pain-relieving effect, a basic principle for conventional SCS is to create paresthesia, presumably by activating myelinated afferent fibers in the dorsal column, which overlap the affected pain region."[2] Achieving the necessary overlap of paresthesia and pain is dependent on several electrical parameters, including amplitude (amperage/voltage), frequency, and pulse width, as well as the choice of which contacts on each lead to employ in delivering the electrical current. Traditional LF SCS is typically programmed clinically between 40 and 90 Hz (cycles per second).

16. Because of this multiparametric, complex programming, close and effective communication between patient and programmer is required, often necessitating time consuming interactions, both during the operating procedure as well as during post-procedure management. This can potentially be even more difficult if there are pre-existing barriers to such communication, such as dementia or psychosocial issues with the patient.

17. Even after successful placement of LF SCS leads, the necessity for concordance of paresthesia and pain exists. Not infrequently, either through lead movement or neural plasticity, the location of the paresthesia can change. This often requires reprogramming, often on multiple occasions, which again mandates close cooperation and communication between

[1] Ex. 3, John Oakley, et al., "A New Spinal Cord Stimulation System Effectively Relieves Chronic, Intractable Pain: A Multicenter Prospective Clinical Study," *Neuromodulation*, 10(3):262-278, 263 (2007).
[2] Ex. 21, Laura Tyler Perryman, "High Frequency Spinal Cord Stimulation: a Review and Introduction to a Novel Wireless Technology for Neuromodulation," *Open J. Surg.* 1(1): 020-025, 021 (2017).

patient and programmer and can, again, be time-consuming and frustrating. If repositioning of the paresthesia cannot be achieved through programming – and the lead has moved – a reoperative attempt at repositioning the lead may be required.

B. Nevro's High-Frequency HF10 Spinal Cord Stimulation

18. Nevro's high-frequency HF10 spinal cord stimulation ("HF10 SCS") is also delivered through leads placed in the epidural space dorsal to the spinal cord and, like all alternating electrical current, can be described by the parameters of amplitude, frequency, and pulse width. However, unlike traditional LF SCS, HF10 SCS is delivered at 10,000 Hz.

19. An important difference of HF10 SCS is that it does not produce a paresthesia. In fact, under normal clinical conditions, the only indication to the patient that the stimulation is working is the reduction in pain.

20. Placement of leads for high frequency SCS is based on anatomy, rather than patient confirmation of paresthesia location. This means that there is no need to have the patient remain awake and alert during the procedure to place the leads. Therefore, the procedure can be done using heavy sedation or even general anesthesia, making it more comfortable and efficient for both patient and physician. This has the added benefit of making the therapy an option for additional patient populations, such as those too anxious to undergo an awake procedure requiring patient feedback.

21. This has greatly reduced the amount of time I need to reserve to perform a lead placement procedure, and made those procedures and the time required much more predictable. More predictable times allow me to schedule and perform more lead placement procedures in a given day, and to otherwise see and treat more patients.

22. The paresthesia-free nature of high frequency SCS also translates into advantages in programming and troubleshooting. As for intraoperative placement, any necessary post-

adjustments to programming do not require immediate patient feedback. The requirement for clear and effective communication between programmer and patient for LF SCS is absent for HF10 SCS. This results in easier and more clear sessions for the patient. It also means more efficient scheduling for the clinic, which allows me to treat more patients in a given day. In addition, the previously mentioned relative barriers, such as dementia and psychosocial difficulties, are much less restrictive, allowing me to treat new patient populations and easing the interactions with these more difficult patients.

23. In addition to the pragmatic advantages enumerated above for high frequency SCS, as discussed in more detail below there also is a dramatic and qualitative improvement in efficacy and quality of life for many patients. My experience, and data in the peer-reviewed literature, supports a very different patient experience with high frequency SCS for neuropathic pain. While LF SCS can have very good results, the usual pain control achieved with HF10 SCS is significantly better. Significantly, these results are achieved without the many drawbacks of paresthesia, addressed below. This is corroborated with the kinds of words patients spontaneously use to describe their outcomes. With LF SCS patients, we would often hear "really good" or "excellent." While patients with HF10 SCS often use phrases like "life changing" and "a miracle." It is very rewarding personally and professionally to hear these sorts of reports from patients.

24. In addition, areas of pain (e.g., low back pain) that have previously been very challenging for LF SCS to treat are much more effectively addressed with HF10 SCS. This again opens up new patient populations for HF10 SCS who I would not have considered good candidates for LF SCS.

III. BENEFITS OF NEVRO'S TECHNOLOGY

A. Superior Pain Relief

25. In my professional opinion, Nevro's technology provides superior pain relief to more patients. This is supported by my own personal experience, the experiences reported to me by my colleagues, and by clinical data. In 2012, Nevro conducted an FDA-monitored clinical study comparing the efficacy of Nevro's Senza device against one of Boston Scientific's traditional low frequency SCS devices that was programmed by BSC representatives and implanted by physicians who regularly implant Boston Scientific devices. This study, the SENZA-RCT study, was the largest prospective randomized clinical trial to assess the treatment of chronic leg and back pain by evaluating the comparative effectiveness of SCS therapies.

26. At the 12-month mark, the results of the SENZA-RCT study were impressive. For back pain, Nevro's HF10 therapy was nearly twice as effective as traditional low frequency SCS therapy administered with the BSC device (84.3% of patients receiving HF10 therapy reported 50% or more pain relief at three months, compared to only 43.8% of patients receiving traditional SCS therapy.)[3] Additionally, HF10 resulted in a 69.2% reduction in back pain using the Visual Analog Scale (VAS) at three months, as compared to only 44.2% for traditional SCS therapy.[4]

27. For leg pain, HF10 therapy was 1.5 times more effective than traditional SCS therapy administered utilizing BSC's device (83.1% of patients receiving HF10 therapy reported 50% or more pain relief at three months, compared to only 55.5% of patients receiving traditional SCS therapy.) Additionally, HF10 resulted in a 72.8% reduction in leg pain at three

[3] Ex. 42, 2016 Nevro 10-K at 7.
[4] *Id*.

months per the VAS scale, compared to 51.5% for traditional SCS therapy. Additionally, HF10 therapy provided effective pain relief without paresthesia.[5]

28. I understand that based on the results of the SENZA-RCT study, the FDA awarded Nevro a "superiority" label, allowing it to market its device as superior to BSC's traditional, low frequency therapy.

29. At the 24-month mark, the results from the SENZA-RCT study continued to be sustained. HF10 demonstrated a superior back pain responder rate of 76.5% versus 49.3% for traditional therapy, and superior leg pain responder rate of 72.9% versus 49.3% for traditional therapy with the BSC device.[6]

30. In my own practice, I have seen a remarkable difference in the amount of pain relief patients enjoy from Nevro's HF10 SCS therapy. The quality and quantity of pain relief are far better than I had experienced with traditional LF SCS therapy. In fact, a few months after I had made the switch to predominately using Nevro's Senza system for my SCS patients, my non-clinical front desk staff came to ask me what was different about the SCS patients. This staff did not know about the switch I had made, only that the patients they were interacting with had received SCS. But my staff could tell from these interactions that something was different and that these patients were doing better than my LF SCS patients in the past. The difference in results for patients was that obvious.

31. The dramatic difference in clinical outcomes between LF SCS and HF10 SCS can be understood through several subpopulations in my practice. I am frequently referred patients with implanted systems (comprised of devices from the three major companies – BSC,

[5] *Id*. at 5.
[6] Ex. 54, Leonardo Kapural, et al., "Comparison of 10-kHz High-Frequency and Traditional Low-Frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain: 24-Month Results From a Multicenter Randomized, Controlled Pivotal Trial," *Neurosurgery* 79(5):667-677, 671 (Nov. 2016).

Medtronic, and Abbott/St. Jude) who have not achieved adequate pain control and wish to simply have the devices removed. These range from systems that were installed years ago and have never provided a benefit, to systems that had achieved some measure of pain control but were no longer effective for some reason. I will almost always convince the patient to first try a "pocket trial," in which the IPG ("battery") pocket is opened and the existing leads are connected to extensions that are brought out through the skin, for the purpose of delivering Nevro's HF10 therapy through those existing leads, giving the patient the opportunity to experience its effects. Of the several dozens of patients in whom I have tried this, almost all of them – with very few exceptions – have experienced dramatic pain relief using HF10 stimulation that they were unable to achieve using LF SCS *through the same leads* in the identical location that failed to provide adequate pain relief using low frequency stimulation.

32. I have heard similar results from many of my colleagues that have tried the Nevro Senza system. They have reported that many patients have had a dramatic improvement in quality of life since being treated with Nevro's therapy, and are often able to resume activities that they had not participated in for years, even while being treated with other forms of SCS therapy. I know several physicians, previously using a competing brand of SCS almost exclusively, who were converted to predominantly using Nevro's HF SCS through close, personal observation of clinical outcomes.

B. <u>Paresthesia-Free</u>

33. There are substantial benefits to physicians and patients as a result of Nevro's HF10 SCS therapy being paresthesia free.

34. Nevro's therapy provides a patient with pain relief without the paresthesia sensation that is intentionally created by paresthesia-based traditional low frequency SCS therapy. Paresthesia is uncomfortable for some patients and can interfere with their mobility and

daily life functions, for example during sleep. The sensation of paresthesia bothers some patients so much that they reject permanent implants. In certain pain patterns, such as with pain solely in the foot, the patient often has to accept a much broader distribution of paresthesia (e.g., the entire leg) to achieve pain control. Many patients find this so undesirable as to preclude use of SCS in their treatment. Moreover, it has often been pointed out in clinical discussions that the focus on paresthesia, and the frequent programming and program management that is a necessary consequence of paresthesia-based SCS, is pointedly contrary to the accepted goal of redirecting the patient's attention away from his/her pain and more toward normal activities of daily living. Paresthesia is also subject to sudden changes, or jolts, as explained below, which can significantly restrict the patient's activity.

35. Spinal cord stimulation leads are placed in the epidural space, outside of the dura containing the cerebrospinal fluid (CSF), overlying the spinal cord. The CSF creates a layer separating the leads and the spinal cord through which the electrical field has to penetrate. The strength of that field, as seen by the spinal cord, depends in part on the distance between the leads and the spinal cord, as determined by the CSF layer.

36. The CSF layer between the SCS leads and the spinal cord is determined by anatomy. However, this distance can vary substantially during normal movements or even coughing, sneezing or straining. Normal movement of the spine changes the relative position of the leads with regard to the spinal cord. In addition, coughing, sneezing or straining transmit pressure directly to the CSF, often causing a similar change in relative position.

37. This change in relative position described above can result in significant changes in the electrical field effecting the spinal cord. For low frequency, paresthesia-based SCS, this means sudden changes in paresthesias – either with loss of efficacy or, the opposite, possibly

painful increases in paresthesia. These effects have been documented to play a role in long-term patient dissatisfaction with SCS and can even make the therapy unusable for certain patients.

38. Positionality is not an issue for high frequency, paresthesia-free SCS. Since no paresthesia is produced, no painful sensations can result from positional variation in the CSF layer. Moreover, because the pain control effects of high frequency SCS are longer term, there is no sudden, immediate loss of pain control with changes in position either. This means that patients do not need to turn their therapy off in order to perform certain activities, such as driving a car. Because LF SCS produces paresthesia, patients are advised to turn the therapy off while driving. And because LF SCS operates quickly, masking the pain with paresthesia as soon as its turned on and providing no masking paresthesia as soon as its turned off, patients are not receiving any relief from their pain when they are driving and the therapy is off.[7]

39. HF10 SCS patients can also engage in a wider-range of activities while still receiving pain relief. To some extent, this is because of the lack of positional variation, causing loss of efficacy or painful paresthesias. In addition, changes in paresthesias during exercise, such as running or swimming, can make LF SCS programming difficult to impossible, as changes cannot be made during the activity. This limitation does not exist for Nevro's HF10 therapy, thus enabling many patients (including many in my own practice) to return to a more active lifestyle.

C. Simpler, More Consistent Lead Placement

40. As described above, there are substantial benefits to physicians and patients as a result of Nevro's Senza system's simpler, more predictable procedure for the placement of leads that does not require a conscious patient during implantation to verify proper lead placement.

[7] Additionally, since HF10 SCS therapy does not work the same way as LF SCS, the therapy does not start and stop immediately. It usually takes several hours after first turning on the therapy to start noticing pain relief, and likewise takes several hours or even days after turning the therapy off before any pain begins to return.

D. Ease of Programming

41. There is a dramatic difference between the amount of programming management, or "overhead" that is required for paresthesia-based SCS and Nevro's high frequency paresthesia-free therapy. In both forms of therapy, after the device is implanted, the patient receives a remote that allows him/her to make adjustments to the therapy, usually to select from among certain set programs, or within certain defined parameter ranges, or simply to turn the therapy off. The patient who receives paresthesia-based therapy will almost always make frequent use of the remote, adjusting the therapy level to accommodate certain body positions or other circumstances, and changing the therapy or even turning it off while driving or sleeping. One study of Medtronic patients who received paresthesia-based spinal cord stimulation therapy found that the patients used the remote to adjust their therapy an average of 210 times per week.[8] In contrast, Nevro has collected data from its patients showing that patients using Nevro's therapy adjust their therapy an average of less than *one* time per week.[9]

42. These results are consistent with what I have observed over the years in my own practice. Patients who receive paresthesia-based therapy make very frequent use of their remote, while patients who receive Nevro's paresthesia-free therapy often just turn on the device and leave it on, sometimes not using the remote at all for weeks at a time. As mentioned above, this allows patients to focus less on their pain and more on the activities of their daily life. It also opens up the possibility of SCS therapy for patients who are not capable, for one reason or another, of effectively managing the frequent programming changes that paresthesia-based therapy normally requires.

[8] Ex. 55, David Schultz, et al., "Sensor-Driven Position-Adaptive Spinal Cord Stimulation for Chronic Pain," *Pain Physician* 15(1):1-12 (Jan./Feb. 2012).

E. Long Felt Need and Expansion of Pool of Suitable Patients

43. There has long been a need for technology that addresses and overcomes the limitations of traditional SCS therapy.

44. First, traditional SCS therapy is not very effective in treating low back pain in the majority of patients. This is a very common problem that impacts many patients. Nevro's high frequency paresthesia free therapy has proven to be effective in treating lower back pain, as described above.

45. The second major drawback of traditional SCS therapy is the sensation of paresthesia that it generates for patients, and the accompanying restrictions that creates, as described in more detail above.

46. Another drawback of traditional SCS therapy is the need for patient feedback during paresthesia-mapping and the attendant requirement to be awake during the procedure, physical and emotional discomfort can be a problem for both patient and physician. As discussed elsewhere in my report, this need to solicit patient feedback during a traditional SCS procedure also creates a risk of error if the patient is unable to communicate clearly or cogently. Removing the need for paresthesia-mapping generates greater efficiency and reduces the risk of error. In fact, some physicians consider programming based on paresthesia-mapping as the hardest part of the procedure. These issues can, and often do, deter certain groups of patients from considering SCS therapy, or alternatively make them less suitable candidates for the therapy.

47. Nevro's HF SCS therapy has significantly expanded the pool of suitable patients, many of whom previously would not have been candidates for SCS therapy. As I have observed in treating my patients, and as the Senza RCT study showed, Nevro's HF SCS therapy addresses the issues above and has proven to be far more effective in treating back pain. This opens up

SCS therapy to many additional patients for whom traditional LF SCS therapy would not be suitable or effective.

48. High frequency, paresthesia-free SCS, with its lower programming overhead, enables the use of this technology in some of these challenging populations. Some people with severe psychosocial issues can have trouble communicating simply and consistently with regard to the degree of pain and location of paresthesia. The same can be true in patients with dementia or other neurocognitive deficits. In the latter, however, there is an additional issue of the ability to independently use the programmer to change programs under different circumstances. With high frequency SCS, the programmer needs to be used far less frequently. Moreover, the question reduces to a simple one of whether the pain is better or not, facilitating clarity of communication. In the patient with dementia, this can also mean a family member is able to use the programmer on behalf of the patient, freeing him or her from an unmanageable burden.

IV. REACTION OF PHYSICIANS AND PATIENTS TO NEVRO'S THERAPY

49. SCS therapy has been available to treat chronic leg pain since the 1970's. In my nearly 10 years using SCS systems with my own patients I have seen multiple new-products launch with boasts of ground-breaking, game-changing improvements, including claims to better treat axial lower back pain. However, in my experience, these claims typically prove to amount to modest improvements at best, or to have limited applicability. As a result, I have been typically wary of claims made by companies about new SCS systems.

50. I first heard about the Nevro Senza SCS system several years ago. As usual, I was initially very skeptical about Nevro's claims to provide paresthesia-free therapy and superior pain relief. As is my usual practice, I decided to wait until there was substantial clinical experience from a broad range of practitioners corroborating these claims before using the technology myself. In fact, I repeatedly declined meeting with Nevro's sales representatives as

an inefficient use of my time prior to clinical verification as above. It would be my inclination to wait and see for quite some time whether the results were real before considering using the technology for my own patients.

51. I first implanted a Nevro Senza SCS system in October 2015. I will often be referred patients, following a successful SCS trial, for permanent SCS implant. A well-respected local pain physician had chosen Nevro HF10 SCS as the modality for the trial, which was successful, and referred the patient to me for permanent implant. This was the sole reason that I finally agreed to meet with Nevro's sales representative. My plan was to follow this patient (and any others that might be referred for permanent Nevro HF10 implant) for an indefinite period of time, gaining personal experience with the treatment and allowing me to make my own evaluation of its efficacy. Despite these plans for an extended period of observation, the dramatic and substantial improvement in patient outcomes over LF SCS was impossible to ignore and resulted in my cutting short this observation period in favor of fully incorporating HF10 SCS into my practice.

52. I began trialing my own patients with Nevro's Senza system and permanently implanting those that had successful trials. The results were so strong that in short order I moved to using Nevro's Senza system for somewhere between 80% and 90% of my SCS patients.

53. Other physicians viewed Nevro's early published results with disbelief. I remember numerous conversations with colleagues at meetings and on faculty at various seminars in which the prevailing sentiment was one of deep skepticism, with a few practitioners adopting a "wait-and-see" attitude. This skepticism was particularly strong because it had previously been generally accepted within the industry that generating paresthesia was necessary for pain relief, and because Nevro's device was operating at a frequency that was much higher

than the 40-90 Hz typically employed in traditional LF SCS devices. Although Nevro's therapy has now gained much broader acceptance and wide industry praise, some of my colleagues continue to express this skepticism even today.[10]

54. This rapid resolution of initial doubt when faced with dramatically superior outcomes using Nevro's HF10 SCS is also consistent with what I know about many of my colleagues' experiences.

55. Following publication of the Senza RCT Study, there has been increasing praise for Nevro's HF10 SCS therapy among doctors and in medical journals. For example, *Neurosurgery*, the official journal of the Congress of Neurological Surgeons, named the Senza RCT 24-month outcomes publication its Top Pain Paper of the Year.[11] This journal is one of two major neurosurgical publications that are read by virtually everyone with interest in the field. With an Impact Factor of 4.889 (2017), *Neurosurgery* is the highest such rated journal in neurosurgery. A minority of neurosurgeons in practice today are involved with SCS, making this journal's selection of the Senza RCT Study for this honor even more dramatic.

[10] For example, some of the comments posted in response to the publication of the 24 month results of the SENZA-RCT study in the journal Neurosurgery—which was awarded "Top Pain Paper of the Year," still continue to express doubt. *See, e.g.*, Ex. 54, Leonardo Kapural, et al., "Comparison of 10-kHz High-Frequency and Traditional Low-Frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain: 24-Month Results From a Multicenter Randomized, Controlled Pivotal Trial," *Neurosurgery* 79(5):667-677, 677 (Nov. 2016) (acknowledging paper is a "welcome addition to the field" but stating "the field of chronic pain is littered with the carcasses of interventions initially thought to be near-panaceas that were later found to be, at the very best, effective for a select group of patients, and, at worst, marginally effective or ineffective in the long-term.").

[11] Ex. 56, Nevro News Release, Neurosurgery Selects the SENZA-RCT 24-Month Outcomes Publication as the Top Pain Paper of the Year (June 15, 2017), http://www.nevro.com/English/Newsroom/Press-Releases/press-release-details/2017/Neurosurgery-Selects-the-SENZA-RCT-24-Month-Outcomes-Publication-as-the-Top-Pain-Paper-of-the-Year/default.aspx.

56. It is not an overstatement to say that Nevro's SCS technology has re-energized the SCS industry and the practice of SCS therapy because of the broader reach of the therapy and its superior results. Since the introduction of Nevro's technology, every major competitor has tried to market a new SCS device or therapy to compete with it.

V. SCS MARKET PENETRATION

57. Prior to Nevro's entry into the SCS market, the market consisted of three players, all major medical device companies: Medtronic, St. Jude (Abbott) and Boston Scientific. All three companies have long established positions in the market, and long-standing relationships with physicians and health care providers, not just in the SCS field, but across a wide variety of medical technologies. In addition, there are also other medical device companies in the market including Stimwave Technologies, Inc. and Nuvectra Corporation. The SCS market is a very difficult market to penetrate, not just because of the size of the competitors but because, for the reasons discussed below, physicians have a deep-seated reluctance to switch to another company's product absent a compelling reason to do so.

58. SCS systems are not an off-the shelf commoditized product, like a catheter or a stent. These are devices that are physically inserted into a patient. The devices each have their own unique characteristics, and my experience in this industry, and from working with all three of these companies as well as Nevro, is that, in the United States, the sales representatives are present in the operating room, alongside the physician during the lead placement and programming of the devices. Over time the sales representative becomes very knowledgeable about the physician's preferences and style, their priorities and work flow, and even their office staff.

59. Once a physician develops a familiarity with a particular company's SCS system, how the device performs over time, and comes to trust the sales representative for that company,

it becomes difficult to persuade the physician to switch to another company's system unless it is truly differentiated in some way. I can say that this is true for my own practice. In the years before I began implanting Nevro's device, I worked primarily with St. Jude. If St. Jude had offered a high frequency paresthesia-free device like Senza, that achieved comparable results, I would never have used Nevro at all.

60. Overcoming these obstacles is even more challenging for a technology like Nevro's HF10 therapy for which there was a built-in skepticism, as discussed above. Nevro's high frequency, paresthesia-free therapy was so different from the accepted method of SCS therapy, employed for decades and thought to be necessary for clinical success, that many physicians were reluctant to try it. While clinical and anecdotal data of Nevro's superior results have gradually won over many of these skeptics, as I have noted above, there are still physicians who remain skeptical even today. If another company were to offer high frequency paresthesia-free therapy that does not perform as well as Nevro's technology, and a skeptical physician were to try it because, for example, it is significantly cheaper than other SCS systems, but the skeptic has a negative experience, the skeptic would find confirmation for their skepticism, and Nevro could forever lose this physician as a potential customer. In the case of Stimwave, if the physician or patient has a negative, or adverse experience as a result of the external battery, they could associate this with implementing high frequency, paresthesia-free therapy and tarnish it with the same brush.

61. In addition to the difficulty in getting physicians to switch from one company to another, in my experience, once leads have been placed into patients from a particular company, they are reluctant to switch to another company's device unless the device is not working for

them. This is a very high bar because a patient generally would have to undergo a new trial and a new operation to make the switch.

VI. COORDINATION BETWEEN PHYSICIANS AND COMPANY REPRESENTATIVES

62. I am very familiar with the interaction between physicians and company representatives in the SCS industry based on my own experience, my discussions with my colleagues, and industry presentations. I have implanted SCS systems manufactured by St. Jude/Abbott, Medtronic, Boston Scientific, and Nevro, and worked with representative from each of these companies. I also did one occipital nerve trial using a Stimwave device. While this involves peripheral nerve stimulation rather than SCS, in my experience the level of involvement of the company representative in these two types of procedures is similar. The Stimwave representative was present for the procedure and involved in the manner generally described below.

63. During a typical SCS procedure, an SCS company representative works very closely with the physician in the operating room. Usually that SCS company representative is a sales representative. Sometimes, during clinical trials, or in support of a difficult case, the SCS company might send a field clinical engineer to support the procedure. The SCS company representative is integral to the procedure for the placement of the leads. It is not an exaggeration to say that if the SCS company sales representative is not able to attend, I would not go forward with a procedure.

64. The lead placement procedure takes place under the ultimate authority of the physician, who has supervision over, and responsibility for, the procedure, including the programming parameters. The SCS company representative, however, does the actual programming of the SCS device. It would be a mistake to think that the physician chooses the

programming parameters of the device from scratch. This is not what happens. Each company's SCS device is different and the physician requires training and information for that particular device before a lead placement procedure can be done. The SCS companies provide a range of recommended and default parameters to optimize therapy with their device to the physician. These include recommendations for frequency, pulse width, amplitude, and lead placement.

65. During the procedure itself, the SCS company representative is programming the device and normally will select at least the initial pulse width, amplitude and frequency. There may be among the physician, the company representative and the patient discussion that results in variations of some of these parameters, but those variations would normally take place within the SCS companies' recommended range. The exception might be a study in which the device is deliberately being programmed to unusual settings outside of the normal ranges. Many physicians rely on the SCS company representative to select the specific parameters to bring about the desired result in the operating procedure. (For example, the physician might say that he or she wants a greater degree of paresthesia in a particular spot, and the SCS company representative would program the device as needed to bring about that result, often called "steering" the stimulation.) Within the spectrum of physician involvement in programming, I tend toward the extreme end of participation when compared to some of my colleagues, yet I still rely completely on the SCS company representative, as the individual who is most familiar with the device, to play a central role in using the programmer and selecting the specific parameters required to achieve the results that I require.

66. Based upon my own experience, and my review of Stimwave materials, I believe that Stimwave SCS representatives have a similar level of involvement to that described above and that Stimwave follows this same model. For example, Stimwave's Freedom Spinal Cord

Stimulation System WaveCrest Programmer User Manual provides that "[o]nly a trained clinical representative may use the WaveCrest Application."[12]

67. The interaction with an SCS company sales representative starts from the representative's attempts to get the physician to evaluate the device. The representative will promote the features of the device and explain its putative advantages over the competition. (The SCS companies themselves, of course, explain and promote the advantages of their therapy at industry conferences and seminars, by sponsoring studies, and in published articles, among other things.) If the representative is successful in engaging the physician to use the device, s/he will become intimately involved as a necessary component of patient care, from initial implant through long-term follow-up.

68. The physician typically starts by positioning the leads and ensuring they are appropriately placed, after which the leads are connected to the external trial stimulator (ETS). For low frequency SCS, careful intraoperative paresthesia-mapping is performed, with close cooperation among physician, company representative and patient being mandatory. The patient is then programmed either post-operatively or on the table, almost universally by the company representative under supervision by the physician. After the leads are in place, the SCS company representative works very closely with the physician to program the SCS device with appropriate parameters for the patient.

69. After the leads are placed, the patient will have follow up visits with the physician to ensure that the device is working properly and providing effective treatment, and to make adjustments as needed. The SCS company representative will always be present for these follow up visits as well, and will re-program the device as needed, in consultation with the physician. It

[12] Ex. 19, Stimwave Wavecrest Programmer User Manual at 3.

is my understanding that most, if not all, of the SCS companies have policies that preclude the sales representatives from meeting with the patients for programming outside of the clinician's office.

VII. AN SCS PHYSICIAN OF ORDINARY SKILL CAN DETERMINE HOW TO DELIVER SCS THERAPY AT THE PARAMETERS CLAIMED IN THE PATENTS

70. Determining the sensory threshold at which a patient experiences paresthesia is a routine part of the procedure of implanting an SCS device and is one that a physician of ordinary skill in the art is very familiar with. The basic procedure for doing so has not changed for some time and was the same in 2007 and 2009 as it is today. The physician will typically work closely with a representative of an SCS device manufacturer, as described above. For example, when implanting a low-frequency device to deliver traditional, paresthesia-based therapy, it is necessary to determine the lowest settings at which a patient will experience paresthesia ("sensory threshold") so that the physician can set the parameters above the threshold and generate the paresthesia needed for the therapy. Often, a physician will determine the highest settings tolerable to the patient ("comfort threshold") and set parameters well below this threshold. To ensure maximum paresthesia coverage, physicians will normally determine the appropriate parameters through an iterative process, where the amplitude is gradually increased from a general starting point. During this process, other parameters such as pulse width and frequency may be changed along with the amplitude. It is a fundamental and routine part of any SCS to determine thresholds (sensory, comfort) of combinations of parameters (frequency, amplitude, pulse width).

71. An SCS physician of ordinary skill in the art would be able to determine the parameters for generating paresthesia-free therapy using the frequency and amplitude ranges provided in the patents. In my clinical practice, I routinely work with SCS company

representatives to determine appropriate parameters for my patients. I have not needed to employ undue experimentation to determine appropriate parameters for my patients.

72. In my experience, using this same methodology, it would not be difficult to identify the appropriate amplitudes within these ranges for frequencies between 1.5 kHz to 100 kHz —the maximum frequency range claimed in the five patents at issue in this action—and determine at which point paresthesia-free therapy can be obtained. This would certainly be true for the full frequency range of the five claims that I understand are at issue in this preliminary injunction motion, which encompasses 3 to 20 kHz. Amplitude, pulse width and frequency all contribute to power. An SCS physician of ordinary skill would know to start the procedure by working with lower power and gradually increasing upwards. The procedure for determining a patient's sensory threshold does not take long—normally from seconds to minutes. It does not add any separate or measurable cost to the implantation procedure and is only a very small part of it. Further, even though there is variability among patients, an SCS physician of ordinary skill would know, with a high degree of confidence, based on their experience and the information provided in the specifications in the patents, that there are certain parameters that will very likely not generate paresthesia, in any given patient. This was the same in 2007 and 2009 as it is today.

73. For high-frequency SCS therapy, there is sometimes a delay of a day or two for the onset of pain relief. This is part of the reason why SCS physicians conduct regular follow-up sessions with patients to determine whether the patient is experiencing pain relief. After the SCS after the operation, and an in-person visit is not immediately required. The patient has a remote control device which allows him or her to adjust the stimulation to different pre-loaded programs or limited settings under the guidance of the physician or sales representative. (This was a normal practice in 2007 and 2009, as it is today). In the case of paresthesia-based therapy, the

patient has to be seen in person by the physician more often during the follow up process for the more complex programming that paresthesia-mapping requires. Because paresthesia-mapping is not required for paresthesia-free SCS therapy, these in-person visits occur less frequently.

74. In my practice, the company representative will follow up directly with the patient by telephone during the days immediately following the operation and make small adjustments to the therapy parameters if the patient is not receiving pain relief or having some other issue with stimulation settings that does not require physician intervention. In this manner, the patient is able to try many different settings, if necessary, before coming back to the physician office for the follow up appointment, which in my case is usually one week after the operation. This is scheduled in my practice as a 15 to 30 minute appointment, and such follow up appointments are included within the cost of the procedure.

75. If for some reason the patient is still not experiencing pain relief, the physician, in conjunction with the representative of the manufacturer, adjusts the parameters of the device using a similar iterative process to the one described above. Delayed onset of pain relief may require more time to make a determination of therapeutic effect, but the steps that the physicians take are no more complicated than for the initial programming. (And, in some ways, the process is simpler for paresthesia free therapy because the programming session – and identification of appropriate parameters for the new program – is not complicated by the need for immediate and accurate reporting by the patient.)

76. A skilled physician working with a SCS representative would be able to determine the parameters to generate paresthesia-free therapy given the frequencies and amplitudes as recited in the claims and the direction that the stimulation to be delivered should

be paresthesia-free. In the SCS field, it is predictable that an iterative process will be required when treating a patient, as was the case in 2007 and 2009.

77. Moreover, the specifications of the patents do provide additional guidance to the practitioner. The specification contained in U.S. Patent No. 8,874, 222 ("the '222 patent") (which is also common to U.S. Patent No. 9,327,127 ("the '127 patent")) describes an iterative process for determining the appropriate parameters.[13] The specification includes suggestions as to how this trial and error process can be "significantly simplified" or "eliminated."[14] There is a lengthy discussion of representative parameters and the implantation and programming process.[15] The specification also does provide exemplary parameters for pulse width, duty cycle, and modulation signal for frequencies of 8 kHz, 9 kHz, and 10 kHz.[16] A skilled physician would know from the specification that 10 kHz is an appropriate starting frequency to provide therapy, based on the description in the patents. The exemplary parameters that are provided in the patents give guidance to a physician of ordinary skill in the art as to starting parameters to try for other frequencies.

78. There is extensive discussion of lead placement in the specifications. The '222 patent specification (common to the '127 patent) explains, among other things that paresthesia-mapping is not required, that compared to traditional SCS therapy, lead placement is much less sensitive, recommends placement in the T9-T12 range, and states that the leads were placed most

[13] Ex. 52,'222 patent at 4:43-5:30.

[14] *Id.* at 5:46-57.

[15] *See, e.g.*, *id.* at 5:63-14:15.

[16] *Id.* at 6:54-7:8, 12:23-32.

frequently at T9-T10, and placement near the midline.[17] Based on these descriptions, and the examples provided, an SCS physician or ordinary skill would be able to determine where to place the leads without undue experimentation.

79. Stimwave recently published a study in which its systems were used to provide high frequency SCS therapy. The study discloses several parameters of the high frequency therapy, including the positioning of the electrodes between the T8 and T11 vertebral levels, a frequency of 10 kHz, a pulse width of 30 microseconds, and paresthesia-free therapy.[18] In my experience working with high frequency SCS therapy with these parameters, the typical amplitude at which the therapy is delivered is below 6 mA.

I declare under penalty of perjury that the foregoing is true and correct. Executed in San Diego, California, on this 16th day of April, 2019.

William Sanford Rosenberg

[17] *See, e.g.*, Ex. 52, '222 patent at 5:46-62, 6:16-42, 6:56-58, 10:50-58, 10:61-65, 11:17-12:22, 17:43-18:50, 25:7-20, 25:22-31.

[18] Ex. 18, Bolash, et al., "Wireless High-Frequency Spinal Cord Stimulation (10kHz) compared with Multiwaveform Low-Frequency Spinal Cord Stimulation in the Management of Chronic Pain in Failed Back Surgery Syndrome Subjects: Preliminary Results of a Multicenter, Prospective Randomized Controlled Study," *Pain Medicine*, 0(0):1-9, 2 (2019).

EXHIBIT A

CURRICULUM VITAE

WILLIAM SANFORD ROSENBERG, M.D.

ADDRESS: Midwest Neurosurgery Associates
2330 East Meyer Blvd, Suite 411
Kansas City, MO 64132
(816) 363-2500

BIRTHDATE: December 27, 1961

BIRTHPLACE: Lancaster, California

MARRIED: June 2, 1985 to Kathi Shaivitz Rosenberg

CHILDREN: Ariane Elizabeth 1988
Alexa Jo 1990

EDUCATION

College of Creative Studies, University of California, Santa Barbara	1982	B.A.
Harvard Medical School, Boston, Massachusetts	1987	M.D.

EMPLOYMENT HISTORY

Postgraduate Training

Massachusetts General Hospital, Department of Surgery, Internship	1987-88
Massachusetts General Hospital, Department of Neurosurgery, Residency Training	1988-92
Massachusetts General Hospital, Department of Neurosurgery, Chief Resident	1993

Faculty Positions

Assistant in Neurosurgery, Massachusetts General Hospital, Boston, Massachusetts	1994
Assistant Professor, Department of Neurosurgery, University of Cincinnati College of Medicine, Cincinnati, Ohio	1994-98
Director, Division of Neurotrauma and Critical Care, University of Cincinnati College of Medicine, Cincinnati, Ohio	1994-97
Research Director, Center for Computational Neurobiology, University of Cincinnati, Cincinnati, Ohio	1995-98

Adjunct Assistant Professor, Department of Aerospace Engineering and Engineering Mechanics, College of Engineering	1996-98
Assistant Professor-In-Residence, University of California School of Medicine, San Francisco, Department of Neurological Surgery	1998-2002
Co-Director, Neurospinal Disorders Program, University of California School of Medicine, San Francisco, Department of Neurological Surgery	1998-2002
Medical Director, Menorah Medical Center CyberKnife Center, Menorah Medical Center, Overland Park, KS	2004-09
Assistant Professor, University of Missouri – Kansas City School of Medicine, Department of Surgery	2017-

Clinical Appointments

Children's Hospital Medical Center, Cincinnati, Ohio	1994-98
Veterans Administration Medical Centers	
Cincinnati, Ohio	1994-98
San Francisco, California	1998-2002
Menorah Medical Center, Overland Park, Kansas	2002-2010
Research Medical Center, Kansas City, Missouri	2002-
St. Luke's Health System, Kansas City, Missouri	2010-2011

HOSPITAL ADMINISTRATION

Founder and Medical Director, Center for the Relief of Pain, Research Neuroscience Institute, Research Medical Center *Mission: To manage complex pain, using a patient-centered, evidence-based approach, through innovation, research, and collaboration, with surgical skill, experience, specialized knowledge, compassion, and empathy, that views each individual's pain experience as unique, in order to improve quality of life.*	2011-
Cancer Committee, Research Medical Center, Kansas City, Missouri	2013-
Informatics Committee, Research Medical Center, Kansas City, Missouri	2013-
Chairman, Department of Neurosurgery, Menorah Medical Center, Overland Park, Kansas	2003-2008
Executive Committee, Menorah Medical Center	2005-2008
Chairman, IRB Committee, Menorah Medical Center	2005-2007
Informatics Committee, Menorah Medical Center	2005-2007

TEACHING EXPERIENCE

Core Clerkship in Neurology and Neurosurgery #110, One and one-half hour ward rounds and lectures, University of California Medical Center, San Francisco, California

Core Clerkship in Neurology and Neurosurgery #110, Neurotrauma Lecture (3 hours), University of California Medical Center. San Francisco, California

Neurosurgery Residents, Intern and Student Teaching, 1-4hrs/day on rounds, in operating room and in conferences, (5 days/week – continuous), University of California Medical Center, San Francisco, California

Faculty Lecture Series for Student Teaching, Department of Neurosurgery, University of California Medical Center, San Francisco, California

RESEARCH SUPERVISION

Graduate Students

Mentor and Thesis Committee member, Ms. Ying Huang, Master of Science, Department of Electrical Engineering, University of Cincinnati, "Quantitative Characterization of the Effect of Medication on Heart Rate Variability of Patients in a Critical Care Environment", 1997.

Mentor and Thesis Committee member, Dr. Hao Hu, Doctor of Philosophy, Department of Aerospace Engineering and Engineering Mechanics, University of Cincinnati, "Modeling of Human Head Impact Response", 1997.

Mentor, Mr. William Palm, Master of Science/Doctor of Philosophy, Department of Mechanical Engineering, University of California, Berkeley, 1999-2000

Post Doctoral

Michael Liebschner, Ph.D.	1999-2000
Praveen Mummaneni, M.D.	1999-2001

RESEARCH POSITIONS

Harvard Medical School, Boston, Massachusetts

Research Fellow in Neuroscience, McLean Hospital (Ole Isacson, Ph.D.)	1991-94
Charles A. Dana Fellow, Department of Molecular Neurogenetics and Neuroscience, Massachusetts General Hospital (Xandra O. Breakefield, Ph.D.)	1990-92
Research Fellow, Department of Immunology (K. Frank Austen, M.D.)	1985-86

University of California, Santa Barbara

President's Undergraduate Research Fellow, Department of Virology (Charles E. Samuel, Ph.D.)	1980-81

GRANT SUPPORT AND CLINICAL RESEARCH

Co-principal investigator with Peter B. Nagy, Ph.D. 4th Biomedical Seed Grant, University of Cincinnati College of Engineering, "Development of an Ultrasonic System for Monitoring Intracranial Changes in Head Injured Patients", $30,000	1996-97
Principal Investigator, HealthSouth Corporation, "Neurotrauma Database Project", $50,000	1996-97
Co-investigator with Lea McLaughlin, Ph.D. and Frank Zemlan, Ph.D., Small Business Innovation Research Program Phase I Grant (DHHS-PHS), "CSF Cleaved-Tau in Traumatic Brain Injury", $99,332	1997-98
Principal Investigator, University of California Academic Senate Grant, "Biomechanics of Vertebroplasty" (Co-investigator: Tony M. Keaveny, Ph.D.), $29,973	1998-99
Principal Investigator, Sofamor-Danek, Inc. Unrestricted Research Funding, $250,000	1998-00
Principal Investigator, Midas-Rex, Unrestricted Research Funding, $50,000/year	1998-2002
Principal Investigator, St. Jude Medical, "Determination of Somatosensory Evoked Potential (SSEP) Collision Testing Parameters During Spinal Cord Stimulation for Characterization of Physiologic Midline/Lead Position Relationship and Dermatome Sensory Thresholds (Protocol C-11-16)."	2011
Principal Investigator, St. Jude Medical, "A Retrospective Evaluation and Data Collection Study to Evaluate the Specificity of the Penta™ Paddle Lead in Patients Implanted with an ANS 16-Channel Implantable Pulse Generator (IPG) (Protocol C-11-04)"	2011
Study Principal Investigator, SI-Bone, "INSITE - Investigation of Sacroiliac Fusion Treatment" – multicenter, randomized, blinded trial of minimally-invasive sacroiliac fusion	2012-2014
Site Principal Investigator, SI-Bone, "SIFI - Sacroiliac Joint Fusion with iFuse Implant System" – multicenter, single arm study of minimally-invasive sacroiliac fusion	2012-2014
Co-Investigator, "Post-operative Pain Control in Spine Surgery Patients With Use of Ketorolac	2014-2015

LICENSURE AND CERTIFICATION

National Board of Medical Examiners	1988
Diplomate, American Board of Neurological Surgeons	1999
Recertified	2009
Massachusetts License	1988
Ohio License	1994

Kentucky License	1994
California License	1998
Kansas License	2002 (current)
Missouri License	2002 (current)

MILITARY EXPERIENCE

Captain, Medical Corps, United States Army Reserve 1990-2000

PROFESSIONAL ORGANIZATIONS

Cancer Pain Research Consortium (Founder) 2013-
- President 2013-16
- Board Member 2013-
- Annual Meeting Co-Chair 2015-16

A multidisciplinary physician group, comprised of practitioners from across North America representing many major cancer centers and large practices, dedicated to generating and promoting interdisciplinary, patient-centered, evidence-based care for cancer-related pain and suffering.

American Association of Neurological Surgeons 1993-
- Abstract Reviewer, 2015 Annual Scientific Meeting

North American Neuromodulation Society 2009-
- Reviewer, *Neuromodulation* 2009-
- Member, Website Committee 2011-15
- Member, Education Committee 2011-15
- Member, Annual Meeting Scientific Program Committee 2018

International Neuromodulation Society 2009-

Reviewer, *Journal of Palliative Medicine* 2017-

American Academy of Pain Medicine 2011-
- Scientific Review and Guidelines Committee 2012-
- Reviewer, *Pain Medicine* 2015-

Congress of Neurological Surgeons 2000-
- CNS University Editorial Board, Pain Section 2013-
- Section Editor (Pain), Editorial Review Board, *Neurosurgery* 2019-

American Board of Neurological Surgeons
- Written Examination Review Committee 2001-2003

AANS/CNS Clinical Outcomes Committee 2000-2002
Representative from Joint Section on Spine and Peripheral Nerves

AANS/CNS Joint Section on Neurotrauma and Critical Care 1994-1998

AANS/CNS Joint Section on Pain 2009-
Executive Council 2013-
Secretary/Treasurer 2015-17
Vice Chair 2017-

AANS/CNS Joint Section on Spine and Peripheral Nerves 1998-
Scientific Program Committee, 2000 Annual Meeting 2000
Guideline Committee 2000-2002
Clinical Outcomes Committee 2000-2002
Executive Committee 2001-2002

American Society for Stereotactic and Functional Neurosurgery 2011-
Education Committee 2014-16

American Society for Clinical Oncology 2012-

Advisory Board, *Spine* (journal) 2000-2002

North American Spine Society 1999-2013

San Francisco Neurological Society 1999-2002

American Brain Injury Consortium 1994-97

Academy of Medicine, Ohio State Medical Association 1994-98
Emergency and Disaster Services Committee 1994-98
Electronic Comm. and Data Interchange Committee 1994-98

Brothers for Life (אחים לחיים) – providing medical care for wounded Israeli soldiers
Medical Advisory Panel 2018-

INDUSTRY AND CONSULTING

Medtronic Sofamor-Danek: Initially consultant with Sofamor-Danek from 1993 and then with Medtronic after acquisition. Evaluated and developed a number of systems for spinal fixation, minimally-invasive surgery and computer-aided image-guided surgery. Participated in business planning and market strategy development. More recently, consultant with Medtronic Neuromodulation on issues regarding neurostimulation and targeted drug delivery.

Medtronic Midas Rex: Consultant from 1997. Evaluated and developed ideas related to robotic surgery and power-driven tools.

Medtronic Neuromodulation: Beginning in 2011, consulting on all aspects of neuromodulation, including deep brain stimulation, spinal cord and peripheral nerve stimulation and intrathecal drug delivery. Chairman of National Cancer Pain Advisory Committee. Faculty for various seminars. Member of the Medtronic Pain Stimulation Business' Innovation Advisory Board.

Depuy/Acromed: Consultant from 1999. Intellectual property resulted in patented instruments for implantation of cervical systems now distributed world-wide. Evaluated and developed systems for cervical fixation.

Spine Wave, Inc.: Founding Consultant and Advisor to clinical start-up with intellectual property regarding intradiscal reconstruction. Revised market and regulatory strategy, developed FDA presentation and assisted in venture capital acquisition. Currently assisting in design and clinical trial architecture of several platform products.

St. Jude Medical: Consulting on all aspects of neurostimulation. Serving on Surgeon Advisory Panel. Faculty for various seminars, events, etc.

Nevro: Consultant on neurostimulation and clinical expert for patent infringement litigation.

SI-Bone: Consultant 2012-14. Involved in all clinical aspects, including refining technique and implant and clinical study design and implementation for minimally invasive sacroiliac joint fusion procedure. Study principal investigator for centerpiece national, multicenter, randomized, blinded study on procedural efficacy.

CyberKnife Associates: Founder and Managing Partner of LLC bringing cutting edge full-body stereotactic radiosurgical equipment (CyberKnife, Accuray Inc.) to Kansas City. Currently in joint venture with HCA.

Menorah Medical Center CyberKnife: Managing Partner of joint venture between CyberKnife Associates, LLC and HCA bringing stereotactic radiosurgery to Kansas City.

KTEC Pipeline Fellow: Selected for the inaugural class of fellowship (www.ktecpipeline.com), sponsored by the Kansas Technology Enterprise Corporation (a public/private venture; www.ktec.com), designed to foster and support entrepreneurship in technology.

Anjon, LLC: Vice President of Business Development. Assisted private equity group Tech Investments, LLC (www.ti-kc.com) in due diligence to acquire medical device contract manufacturer, Anjon, LLC (www.anjoninc.com). Responsible for developing strategic contacts and partnerships for Anjon, as well as participating with engineering team in executing projects.

OsteoGeneX: Chief Medical Officer to clinical startup (www.osteogenex.com) developing bone growing technology for both systemic and local therapies. Responsible for all facets of startup, including determining strategy and business model, helping design and deliver presentations, raising venture capital, overseeing clinical strategies, physician relations and regulatory issues, assembling and chairing Scientific Advisory Board.

Patient Resource: First non-oncologist appointed to the National Advisory Board (www.patientresource.com). Revised and developed pain content for all materials related to cancers that generate pain as a dominant symptom. Supervised content selection, organization and creation for new *Cancer Pain Guide*, in collaboration with the Cancer Pain Research Consortium.

Have evaluated business opportunities and clinical intellectual property for a number of venture capital funds, including **Canaan Partners**, **MPM Capital** and **Medica Venture Partners.**

PATENTS

Rosenberg et al., Spinal Rod Approximator, US Application Num 10/352,687, Filed June 28, 2003, Pub. No. US 2004/0147936 A1

Ellies and Rosenberg, Gamma-lactam compounds for promoting bone growth, US Application Num 12/472,134, Filed May 26, 2009, Patent Number 8,080,575

Ellies and Rosenberg, Vinpocetine And Eburnamonine Derivatives For Promoting Bone Growth, Treating Renal Damage And Cancer, And Devices Thereof, US Application Num 12/494,670, Filed June 30, 2009, Patent Number 8,198,292 B2

MEETINGS, LECTURES, TALKS, PAPER PRESENTATIONS

Invited Speaker, *How and Why to Integrate Neuromodulation Into Your Spine* Practice, AANS/CNS Joint Section on Pain Biennial Meeting, Miami, Florida, March 13-14, 2019

Invited Speaker, *Neurosurgical Treatment of Pain*, Pain Service, Brigham & Women's Hospital, Harvard Medical School, October 27, 2017

Visiting Professor, *Neurosurgical Treatment of Pain*, Neurosurgery Grand Rounds, Massachusetts General Hospital, Harvard Medical School, October 26, 2017

Visiting Professor, *Neurosurgical Treatment of Pain*, Neurosurgery Grand Rounds, Brigham & Women's Hospital, Harvard Medical School, October 25, 2017

Invited Faculty, *Techniques and Indications for Cordotomy*, Interventional Cancer Pain Symposium, Memorial Sloan Kettering Cancer Center, New York, New York, September 8, 2017

Course Director, *Neuroablation and Neuromodulation for Pain: Expanding the Neurosurgeon's Toolbox*, AANS/CNS Joint Section on Pain Biannual Meeting, Chicago, Illinois, May 19-20, 2017

Invited Faculty, *Therapies for Cancer Pain*, Neuromodulation Cadaver Course for Advanced Implantable Therapies, North American Neuromodulation Society 20th Annual Meeting, Las Vegas, Nevada, January 19, 2017

Moderator, *Complex Regional Pain Syndrome and Other Challenging Cases*, North American Neuromodulation Society 20th Annual Meeting, Las Vegas, Nevada, January 20, 2017

Moderator, *Cancer Pain in the Hot Seat: A Multidisciplinary Expert Panel Grappling with Real-life Clinical Issues* (joint with the Cancer Pain Research Consortium), North American Neuromodulation Society 20th Annual Meeting, Las Vegas, Nevada, January 21, 2017

Moderator and Organizer, 2016 Symposium on Chronic and Cancer Pain: State-of-the-Art Management, Sheraton Overland Park Hotel, Overland Park, Kansas, November 4, 2016

Invited Faculty, *Surgical Management of Non-Malignant Neuropathic Pain*, 2016 Symposium on Chronic and Cancer Pain: State-of-the-Art Management, Sheraton Overland Park Hotel, Overland Park, Kansas, November 4, 2016

Invited Faculty, *Neurosurgical procedures for cancer pain – who, what and when*, Cancer Pain Research Consortium Annual Meeting, Scottsdale, Arizona, April 16, 2016

Moderator, *Neuromodulation and imaging in the cancer pain patient*, Cancer Pain Research Consortium Annual Meeting, Scottsdale, Arizona, April 16, 2016

Invited Faculty, *Best Practices: Pancreatic Cancer Pain*, Cancer Pain Research Consortium Annual Meeting, Scottsdale, Arizona, April 15, 2016

Invited Faculty, *Vertebral metastases: a multidisciplinary approach*, Cancer Pain Research Consortium Annual Meeting, Scottsdale, Arizona, April 15, 2016

Invited Faculty, *Cancer Pain*, Neuromodulation Workshop for Pain Fellows and Neurosurgery Residents, North American Neuromodulation Society 19th Annual Meeting, Las Vegas, Nevada, December 10, 2015

Invited Faculty, *Intrathecal Therapy Management*, Neuromodulation Workshop for Pain Fellows and Neurosurgery Residents, North American Neuromodulation Society 19th Annual Meeting, Las Vegas, Nevada, December 10, 2015

Invited Faculty, *Intrathecal Therapy Management*, Certificate of Attendance Neuromodulation Workshop, North American Neuromodulation Society 19th Annual Meeting, Las Vegas, Nevada, December 10, 2015

Invited Speaker, *Neurosurgical Approaches to Treating Pain*, Pain Symposium, Kansas City Southwest Clinical Society, Overland Park, Kansas, October 30, 2015

Invited Faculty, *Complicated Cases*, Cancer Pain Research Consortium Annual Meeting, Scottsdale, Arizona, April 24, 2015

Invited Faculty, *Pelvic Sarcoma*, Cancer Pain Research Consortium Annual Meeting, Scottsdale, Arizona, April 24, 2015

Invited Faculty, *Multidisciplinary Treatment of Cancer Pain*, Medtronic Sponsored Lunch, Cancer Pain Research Consortium Annual Meeting, Scottsdale, Arizona, April 24, 2015

Invited Faculty, *Cancer Pain*, Neuromodulation Workshop for Pain Fellows and Neurosurgery Residents, North American Neuromodulation Society 18th Annual Meeting, Las Vegas, Nevada, December 11, 2014

Invited Faculty, *Intrathecal Therapy Maintenance*, Certificate of Attendance Neuromodulation Workshop, North American Neuromodulation Society 18th Annual Meeting, Las Vegas, Nevada, December 11, 2014

Invited Faculty, *Advanced Neurosurgical Procedures for Cancer Pain*, Midwest Pain Society 38th Scientific Meeting, Chicago, Illinois, October 24, 2014

Invited Speaker, *Complex Cancer Pain Cases*, Management of Cancer Pain (Section on Pain), Congress of Neurological Surgeons 14th Annual Meeting, Boston, Massachusetts, October 20, 2014

Co-moderator, *Management of Cancer Pain,* Section on Pain, Congress of Neurological Surgeons 14th Annual Meeting, Boston, Massachusetts, October 20, 2014

Invited Faculty, *Neurosurgical Options for Treatment of Cancer Pain*, Third Annual Cancer Pain Conference, Phoenix, Arizona, April 25, 2014

Invited Faculty, *Optimizing Patient Care Through Collaboration*, Third Annual Cancer Pain Conference, Phoenix, Arizona, April 25, 2014

Invited Presentation, Children's Mercy Hospital, *Neurosurgical Treatment of Pediatric Cancer Pain*, Kansas City, Missouri, March 11, 2014

Grand Rounds, Department of Neurosurgery, Kansas University Medical Center, *Neurosurgical Treatment of Cancer Pain*, Kansas City, Missouri, January 10, 2014

Moderator, *Cancer Pain: The Continuum of Care*, North American Neuromodulation Society 17th Annual Meeting, Las Vegas, Nevada, December 6, 2013

Moderator, *Treatment of Neuropathic Pain Symposium*, Kansas City Southwest Clinical Society 91st Annual Meeting, Overland Park, Kansas, November 1, 2013

Invited Speaker, *Role of Neuromodulation in the Treatment of Neuropathic Pain*, Treatment of Neuropathic Pain Symposium, Kansas City Southwest Clinical Society, Overland Park, Kansas, November 1, 2013

Invited Speaker, *Efforts to Control Prescription Drug Abuse: The Other Side of the Coin*, National Association of State Controlled Substances Authorities 29th Annual Educational Conference, Kansas City, Missouri, October 24, 2013

Invited Speaker, *Profitably Integrating Spinal Cord Stimulation Into Your Practice*, Neuromodulation 2013: What Every Neurosurgeon Needs To Know, Congress of Neurological Surgeons Annual Meeting, San Francisco, California, October 20, 2013

Invited Speaker, *The Difficult Paddle Lead*, Neurosurgical Approaches to the Pain Patient, Congress of Neurological Surgeons Annual Meeting, San Francisco, California, October 19, 2013

Invited Speaker, *Neurotechnology – Leaders in Industry and Medicine Meet Promising Israeli Companies*, Ernst & Young JOURNEY Conference, Tel Aviv, Israel, October 17, 2013

Invited Faculty, *Management of Chronic Intractable Cancer Pain: A Dialogue* (Medtronic), Dallas, TX, January 2013

Invited Lecturer, *Neuroablative Techniques for the Treatment of Pain*, Southwest Clinical Society, Overland Park, Kansas, November 2, 2012

Invited Faculty, *Management of Chronic Intractable Cancer Pain: A Dialogue* (Medtronic), Minneapolis, MN, October 2012

Grand Rounds, Department of Neurosurgery, North Shore – Long Island Jewish Health System, *Neurosurgical Treatment of Cancer Pain*, Manhasset, New York, October 2012

Invited Faculty, *Cancer Pain Forum*, Scottsdale, Arizona, April 2011

Grand Rounds, Department of Neurosurgery, Johns Hopkins School of Medicine, *Image-Guided Spinal Surgery*, Visiting Professor, Baltimore, Maryland, December 2000

Congress of Neurological Surgeons 50th Annual Meeting, *Spinal Infections*: *Contemporary Diagnosis and Management*, Invited Lecturer, San Antonio, Texas, September 2000

Fundamental Principles & Techniques of Spinal Surgery, *Discogenic Back Pain – Diagnosis, Work-Up, and Patient Management*, Invited Lecturer, Barrow Neurological Institute, Phoenix, Arizona, June 2000

Fundamental Principles & Techniques of Spinal Surgery, *Safe Navigation of the Spine*, Invited Lecturer, Barrow Neurological Institute, Phoenix, Arizona, June 2000

American Association of Neurological Surgeons Annual Meeting, "Anterior Lumbar Interbody Fusion" in *Lumbar Spine Fusion: Indications, Patient Selection and Current Techniques*, Invited Faculty, San Francisco, California, April 2000.

American Association of Neurological Surgeons Annual Meeting, *Low Back Pain*, Invited Lecturer, San Francisco, California, April 2000.

Practical Innovations in Image Guided Surgery, *Intraoperative 3D and Fluoroscopic Guided Spinal Surgery*, Program Chairman; University of California, San Francisco, California, April 2000.

Current Techniques in Lumbosacral Fixation: Minimizing Complications in Spine Surgery, *Pseudarthrosis*, Invited Faculty; University of California, San Francisco, California, April 2000.

Current Techniques in Lumbosacral Fixation: Minimizing Complications in Spine Surgery, *Transforaminal Lumbar Interbody Fusion*, Invited Faculty; University of California, San Francisco, California, April 2000.

Congress of Neurological Surgeons 49th Annual Meeting, *Lumbosacral Fusions: Cages, Dowels, and Pedicle Screws,* Invited Faculty, Boston, Massachusetts, October-November 1999

Congress of Neurological Surgeons 49th Annual Meeting, "Operative Treatment of Spinal Infections" in *Spinal Infections: Contemporary Diagnosis and Management*, Invited Lecturer; Boston, Massachusetts, October-November 1999

Clinical Neurosciences by the Bay, *Surgical Treatment of Myelopathy*, San Francisco, California, September 1998

Grand Rounds, Dept. of Emergency Medicine, University of Cincinnati College of Medicine, *Management of Intracranial Pressure*, Cincinnati, Ohio, October 1996

Pulmonary Critical Care Lecture Series, University of Cincinnati College of Medicine, *Intracranial Hypertension*, Cincinnati, Ohio, April 1996

Emergency Medicine Symposium 1995, *Emergency Management of Head Injuries*, Cincinnati, Ohio, May 1995

Advances in Clinical Neurosurgery, Mayfield Winter Neurosurgical Symposium, *Demonstration of Cervical Spine Stabilization*, Snowmass, Colorado, March 1995

Advances in Clinical Neurosurgery, Mayfield Winter Neurosurgical Symposium, *Lumbar Spine Stabilization Techniques*, Snowmass, Colorado, March 1995

Orthopedic Grand Rounds, The Christ Hospital, *Post-laminectomy Kyphosis*, Cincinnati, Ohio, January 1995

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Hu H, Nayfeh AH, Rosenberg WS: Modeling of Human Brain Movability During Impact. **Proceedings of 5th International LS-DYNA Users Conference**, 1998

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Kager C, Weiner N, Rosenberg WS: Analysis of the Codman Ti-Frame System for Posterior Cervical Stabilization, **Joint AANS/CNS Section on Disorders of the Spine and Peripheral Nerves 15th Annual Meeting,** Orlando, Florida, February 1999

Chun J, Rosenberg WS: Use of Titanium Mesh and Vertebral Autograft in the Reconstruction of Anterior Spinal Column **Joint AANS/CNS Section on Disorders of the Spine and Peripheral Nerves 16th Annual Meeting,** Palm Desert, California, February 2000

Liebschner MAK, Rosenberg WS, Keaveny TM: Effects of Bone Cement Volume and Distribution on Vertebral Body Stiffness Recovery after Vertebroplasty, **Orthopedic Research Society 46th Annual Meeting**, Orlando, Florida, March 2000. **["Best Basic Science Study" Award for New Young Investigators]**

Mummaneni PV, Haddock SM, Yeh O, Keaveny TM, Rosenberg WS: Low Cycle Fatigue Behavior of Human Vertebral Trabecular Bone, **Orthopedic Research Society 46th Annual Meeting**, Orlando, Florida, March 2000.

Mummaneni PV, Haddock SM, Yeh O, Keaveny TM, Rosenberg WS: Low Cycle Fatigue of Human Vertebral Trabecular Bone. **American Association of Neurological Surgeons 68th Annual Meeting,** San Francisco, California, April 2000

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Mummaneni PV, Rosenberg WS: Transforaminal Lumbar Interbody Fusion: A Clinical Series, **Congress of Neurological Surgeons 50th Annual Meeting**, San Antonio, Texas, September, 2000.

Mummaneni PV, Rosenberg WS: Transforaminal lumbar interbody fusion: the UCSF experience, **Spine+Science+Management Symposium**, New Orleans, Louisiana, November, 2000.

Rosenberg WS, Palm WJ IV, Keaveny TM: Effect of Implant and Bone Material Properties on Load Transfer in Cylindrical Interbody Cages: A Computational Study, **AANS/CNS Section on Disorders of the Spine and Peripheral Nerves 17th Annual Meeting**, Phoenix, Arizona, February, 2001.

Mummaneni P, Haddock S, Liebschner M, Keaveny T, Rosenberg W: Biomechanical Evaluation of a Double-Threaded Pedicle Screw in Elderly Vertebrae, **AANS/CNS Section on Disorders of the Spine and Peripheral Nerves 17th Annual Meeting**, Phoenix, Arizona, February, 2001.

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Koffman BH, Rosenberg WS, Nguyen DM, Pointer AM, Cates JA, Edwards FM: Large Lung and Liver Tumors Can Be Treated with CyberKnife, **CyberKnife Users' Meeting**, Carlsbad, California, February 2006

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Rosenthal HG, Rosenberg WS, Koffman BH: Stereotactic Radiosurgery in the Treatment of Soft Tissue Sarcomas, **Musculoskeletal Tumor Society**, Key West, Florida, June 2006

Rosenberg WS: Spinal Anesthesia for Placement of Surgical Spinal Cord Neurostimulation Paddle Electrodes: A Case Series, **North American Neuromodulation Society**, Las Vegas, Nevada, December 2011

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Clark CM, Rosenberg WS: Intrathecal Medicine Toxicity Presenting as Reversible Brown-Sequard Syndrome, **North American Neuromodulation Society**, Las Vegas, Nevada, December 2013

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CERTIFICATE OF SERVICE

I hereby certify that on April 17, 2019, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on April 17, 2019, upon the following in the manner indicated:

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